

REMARKS/ARGUMENTS

1. *Status of the Claims*

With this Amendment, claims 1-5 have been canceled, and claims 16-21 have been added. Thus, claims 16-21 are pending with the entry of this Amendment.

Support for the amendments to the claims can be found throughout the specification, the drawings, and the claims as originally filed. No new matter is introduced by this Amendment.

2. *Rejection under 35 U.S.C. §§ 102(b) and 103*

The Examiner rejected claims 1-5 as allegedly anticipated by or, in the alternative, obvious over Zaille *et al.* under 35 U.S.C. § 102(b) and 35 U.S.C. § 103, respectively. To the extent that the examiner rejects the newly added claims, Applicants respectfully traverse the rejection.

It is Applicants' understanding based on a phone conversation with the Examiner that the claims as amended are not anticipated.

For a claim to be anticipated, every element of the claim must be expressly or inherently described in a single prior art reference. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1997).

As amended, claims 16-21 provide methods for generating high amylose wheat starch by modifying the wheat to lack the SGP-1 protein. Zaille *et al.* does not teach or suggest a method of generating starch from a wheat plant lacking the SGP-1 protein, as recited in claims 16-21. Indeed Zaille, *et al.* does not even suggest a role for SGP-1 in starch production.

Since Zaille *et al.* does not teach or suggest a method of generating starch from a wheat plant lacking the SGP-1 protein, the reference cannot anticipate claims 16-21. Therefore, Applicants respectfully request withdrawal of this rejection.

2. *Written Description Rejection*

Claims 1-4 were rejected as allegedly claiming subject matter not described in the specification in such a way as to reasonably convey that the inventors were in possession of the claimed invention. It is Applicants' understanding based on a phone conversation with the Examiner that the claims as amended satisfy the written description requirement.

The Examiner based the rejection on the reasons provided in the office action of September 23, 2003. According to the Examiner, to meet the written description requirement for a genus, a representative number of species must be provided in the specification. The Examiner acknowledges that there are other ways to meet the written description requirement, but argues that they require description of the "complete structure" of the genus, which is impossible for plants. The Examiner further argues that it is not possible to describe the claimed products because there may be an infinite combination of parents that can provide progeny that can produce the claimed starch. Moreover, the Examiner argues that one of skill would not have been able to predict all of the resulting phenotypes of plants that could produce the claimed starch. Applicants respectfully traverse the rejection.

The present application describes the relevant characteristics of the claimed invention, including a correlation between structure (i.e., mutation of a well-known gene) to function (high amylose content), thereby meeting the written description requirement.

The present invention relies on the simple genetic principle that the absence of a gene encoding an active enzyme SGP-1 results in plants that have seed with a high (greater than 35%) amylose content. The claims under examination are directed to starch from such plants. Thus, all that is necessary to describe the claimed genus are the following elements: starch, wheat, SGP-1 and amylose. While it is impossible to "completely" describe a plant, it is clear that those of skill in the art would not question that "starch" or "wheat" are readily recognized in

the art. Similarly, it is readily understood what "amylose" refers to and how to measure its quantity. *See*, paragraph spanning pages 6-7 of the specification.

Finally, the SGP-1 enzyme and methods for its detection have previously been described in the art. *See*, Yamamori and Endo, *Theor. Appl. Genet.* 93:275-281 (1996), cited on pages 3-4 of the present application. As detailed below, the application sets forth a number of ways by which plants modified to lack SGP-1 can be created. Moreover, plants lacking various SGP-1 isozymes are readily identifiable. Thus, those of skill in the art would readily understand from the specification that the inventors had possession of the full scope of the claimed invention.

The Examiner states that the relevant analysis of written description is whether the application describes the phenotype of the plant from which the starch is derived. *See*, September 23, 2003 Office Action, page 5. The Examiner states that "millions of possible phenotypes" are encompassed by the claims and so are not adequately described. *See*, page 3 of the September 23, 2003 Office Action. It is not completely clear to what the Examiner refers. It is true that the wheat plants modified to lack SGP-1 can vary greatly in their overall genotype. For example, the disease resistance of such plants could vary greatly. This fact is not relevant to the written description analysis. It is always true that "comprising" claims can include additional aspects (i.e., "millions" of different aspects). Nevertheless, if the relevant characteristics of the claimed invention are clearly described in the specification, and they are in this case, then the written description requirement has been met.

It is Applicants' understanding that the claims as drafted fulfill the written description requirement of 35 U.S.C. § 112. Accordingly, Applicants respectfully request withdrawal of the rejection.

3. ***Enablement Rejection***

The Examiner bases the rejection on the reasons provided in the Office Action of September 23, 2003 and the Office Action of March 24, 2004.

To establish a *prima facie* case of non-enablement, the Examiner must show that undue experimentation would be required to make and use the claimed invention. As set forth in MPEP § 2164.06, even if the practice of the claimed invention requires a considerable amount of experimentation, it is not necessarily "undue" experimentation:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) (citing *In re Angstadt*, 190 USPQ 214 (CCPA 1976).

The Examiner argues that "[d]ue to genotypic variance, dominance deviations, epistatic interactions and factors affecting heredity, genetic variance must be experimentally determined," resulting in undue experimentation (March 24, 2004 Office Action at page 3). However, for reasons similar to those discussed above and the following, a *prima facie* enablement rejection has not been established.

The only genetic factor at issue is the presence or absence of the functional gene encoding SGP-1. As the application teaches, wheat has a hexaploid genome and therefore has three pairs of chromosomes. *See*, page 3, line 30 of the present application. Each pair of chromosomes can carry an active SGP-1 allele. *See*, paragraph spanning pages 3-4 of the present application. The three pairs of chromosomes carry genes encoding SGP-A1, SGP-B1 and SGP-D1, respectively. SGP-A1, SGP-B1 and SGP-D1 are isozymes that are readily differentiated by SDS electrophoresis analysis. *See*, page 3, line 30 of the present application *citing* Yamamori and Endo, *Theor. Appl. Genet.* 93:275-281 (1996) (cited in IDS).

Generation of a wheat plant modified to lack SGP-1 entails simply identifying plants that lack an active copy of at least one of SGP-A1, SGP-B1 and SGP-D1 and then crossing the plants with plants that lack an active copy of a different gene selected from SGP-A1, SGP-B1 and SGP-D1 to create a wheat plant that lacks two of the active genes. *See, e.g.*, page

8, line 16 to page 10, line 13 of the present application. A wheat plant lacking the third gene of SGP-A1, SGP-B1 and SGP-D1 is then crossed to the progeny of the first cross to produce a plant without any active gene encoding SGP-A1, SGP-B1 or SGP-D1. *See, id.*

Those of skill in the art, reading the present specification, would understand that the application describes some wheat lines that have been identified to lack at least one SGP-1 gene. *See*, page 10, lines 3-13 of the present application. In addition, it is a simple matter to screen through additional wheat lines to identify those lacking at least one SGP-1 isozyme using SDS electrophoresis. Thus, generation of a wheat plant modified to lack SGP-1, at most, only requires routine methods well known to plant breeders of ordinary skill in the art.

The Examiner suggests that "genotypic variance, dominance deviations, epistatic interactions and factors affecting heredity" affect enablement of the present claims but does not explain why this is so. Nor does the Examiner explain the relationship of such issues to the claims at hand. The reference cited by the Examiner describes how to analyze populations genetically, but does not appear to question that modifying a gene to lack a dominant allele of a gene such as SGP-1 would be affected by such factors. Absent an explanation of the relevance of the Fehr citations, Applicants respectfully submit that it is irrelevant to the patentability of the present claim.

Although not formally discussed in the phone interview, Applicants believe that the rejection should be withdrawn for reasons similar to those in section 2 and for reasons discussed in this section. Accordingly, Applicants respectfully request withdrawal of the rejection.

Appl. No. 09/325,819
Amdt. dated June 18, 2004
Reply to Office Action of March 24, 2004

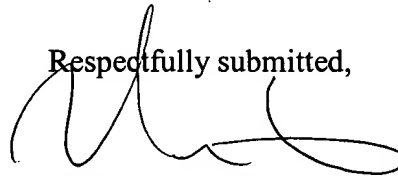
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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